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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
COTTON, ABIGAIL MANDA	

ART UNIT	PAPER NUMBER
1617	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/505,178	PINZA, MARIO	
	Examiner	Art Unit	
	Abigail M. Cotton	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 December 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-20* is/are pending in the application.

4a) Of the above claim(s) *8-10 and 18-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3-7 and 11-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This Action is in response to the amendment submitted on December 15, 2005. Claims 1 and 3-20 are pending in the application. Claims 8-10 and 18-20 are being withdrawn from consideration as drawn to a non-elected invention. Accordingly, claims 1, 3-7 and 11-17 are being examined on the merits herein.

The objection to claim 4-8 under 37 CFR 1.75(c) as being in improper form is being withdrawn in view of Applicant's amendment to the claims.

The rejection of claim 8 under 35 U.S.C. 112, second paragraph, is being withdrawn, as this claim is being withdrawn from consideration due to Applicant's amendment of the claim to recite a constructively non-elected invention, as discussed in further detail below.

The rejection of claims 1 and 8 under 35 U.S.C 102(b) as being anticipated by the article by O'Connor et al. is being withdrawn in view of Applicant's amendment to claim 1, and the withdrawal from consideration of claim 8 for the reasons cited below.

Applicant's arguments regarding the rejection of the claims under 35 U.S.C. 103(a) over Cavanaugh, Jr. and O'Connor et al, and further in view of Bianchi et al have been fully considered but they are not persuasive.

Election/Restrictions

Newly amended claim 8 and newly submitted claims 9-10 and 18-20 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The invention as originally presented and the newly presented invention are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the product as claimed can be used in a materially different process of using the product, such as in the treatment of other inflammatory disorders treatable by orally administered NSAIDs.

Because these inventions are distinct for the reasons given above and the search required for the originally presented invention is not required for the new invention, restriction for examination purposes as indicated is proper. It is noted that while the searches of the inventions may be overlapping, there is no reason to believe that the searches would be co-extensive. In searching the originally presented invention, the Examiner has focused on the patentability of the product itself, and not the process of using. Conversely, in searching the newly presented invention, the

Examiner would have to focus on the patentability of the process and not the product itself. Accordingly, a search for both groups would pose an undue burden on the Office.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 8-10 and 18-20 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

The examiner has restricted between product and process claims. The constructively elected claims are directed to the product. Should the product claim be found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to

be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3-4, 6-7, 11-14 and 16-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,626,838 to Cavanaugh, Jr., issued May 6, 1997, in view of the article "Preparation and Characterisation of a Range of Diclofenac Salts" by O'Connor et al.

Cavanaugh, Jr. teaches methods for prevention or treatment of primary and recurring squamous cell carcinoma by topical administration to the oral cavity or oropharynx of an effective amount of an NSAID (see abstract, in particular.) Cavanaugh, Jr. teaches that it is known to topically administer NSAIDs such as diclofenac for the treatment of various diseases and conditions (see column 1, lines 44-65, in particular.) Cavanaugh, Jr. teaches that the composition can be in the form of a toothpaste, mouthwash, mouthspray and the like (see column 3, lines 40-42, in particular.) Cavanaugh, Jr. teaches that water can comprise from 2 to 99% of the compositions, such as from about 45% to about 95% of a mouthwash (see column 5,

lines 44-56, and Examples 3, 4 and 5 in particular.) Accordingly, Cavanaugh, Jr. teaches an aqueous composition having an NSAID.

Cavanaugh, Jr. furthermore teaches that the concentration of the NSAID in the solution is selected to provide an effective concentration of the NSAID solution in the mouth in contact with the oral cavity, and may be selected with respect to factors such as the dilution that occurs in the mouth from saliva (see column 5, lines 1-20, in particular.) Cavanaugh, Jr. teaches that a suitable concentration of the NSAID may generally be from about 0.02% to about 4% (see column 5, lines 10-15, in particular.) Cavanaugh, Jr. furthermore teaches that a suitable pH of the composition can be from about 2 to about 9 (see column 5, lines 24-27, in particular.) Thus, Cavanaugh teaches a range that encompasses and/or overlaps with that recited in claims 1 and 11-12. Furthermore, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the concentration of NSAID provided in the composition, according to the guidance provided by Cavanaugh, to provide a composition having desired properties. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Regarding claims 3 and 13, Cavanaugh, Jr. teaches that sweetening agents such as saccharine salts and acesulfame (see column 6, lines 40-48, in particular.)

Regarding claims 4 and 14, Cavanaugh, Jr. teaches that the composition can comprise preservatives such as benzoates and exemplifies compositions with sodium benzoate (see column 7, lines 5-15, and Examples 3, 4 and 5, in particular.)

Regarding claims 6 and 16, Cavanaugh, Jr. teaches that the composition can comprise flavoring agents, such as menthol and wintergreen oil (see column 6, lines 32-39, in particular.)

Regarding claims 7 and 17, Cavanaugh, Jr. exemplifies compositions with FD&C Blue (see Examples 3, 4 and 5, in particular.)

Cavanaugh, Jr. does not specifically teach providing a composition having an NSAID that is diclofenac in the percent concentration and pH ranges as recited in claims 1 and 11.

O'Connor et al. teaches that diclofenac is a potent anti-inflammatory drug that is therapeutically used (see page 164, paragraph bridging right and left hand columns, in particular.) O'Connor et al. furthermore teaches the preparation of the Tris(hydroxymethyl)aminomethane salt of diclofenac (DTRIS), which is the tromethamine salt of diclofenac (see pages 164-166, in particular.) O'Connor et al. teaches formulating an aqueous solution of the tromethamine salt of diclofenac

(DTRIS), having a pH of 7.13 and a saturated solubility of about 3.95 mM (see page 172, paragraph bridging right and left hand columns, in particular) and thus is soluble in an amount up to 3.95 mM, which is equivalent to about a 0.16% w/w solution of the diclofenac tromethamine salt. Accordingly, O'Connor et al. teaches the solution can have a solubility up to an amount that meets the range limitation of claim 11, and that overlaps with the amount recited in claim 1, as well as a pH that meets the limitation of claim 1. Furthermore, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of the diclofenac tromethane salt provided in the composition, according to the guidance provided by O'Connor et al, to provide a composition having desired properties, such as a desired saturated solution. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Accordingly, one of ordinary skill in the art at the time the invention was made would have been motivated to provide the tromethamine diclofenac salt of O'Connor et al. the oral treatment composition of Cavanaugh, Jr., because Cavanaugh, Jr. teaches that the composition comprises an effective amount of an NSAID to treat oral disorders, and O'Connor et al. teaches that diclofenac is a NSAID capable of treatment and can be formulated in aqueous compositions. Accordingly, one of ordinary skill in the art would have been motivated to provide the diclofenac salt taught by O'Connor et al. in the

composition of Cavanaugh, with the expectation of providing a composition for treating oral disorders having a suitable formulation of the diclofenac NSAID.

Furthermore, regarding the specific concentration percentage of the diclofenac tromethamine salt in the composition as recited in claims 1 and 11-12 and the pH ranges as recited in claims 1 and 11, it is considered that one of ordinary skill in the art would have found it obvious to vary the pH and concentration of the diclofenac tromethamine salt to obtain a desired effective amount of the NSAID, particularly in light of the teachings of Cavanaugh, Jr. and O'Connor et al. For example, one of ordinary skill would have found it obvious to vary the concentration to arrive at a desired effective concentration with regards to any dilution effects from saliva, as taught by Cavanaugh, Jr, and to vary the concentration to achieve solubility of the diclofenac tromethamine salt, as taught by O'Connor et al. Also, as Cavanaugh teaches that a pH of from 2 to 9 is suitable for the composition, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the pH of the composition, according to the guidance provided by Cavanaugh and O'Connor et al, to provide a composition having the desired properties. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Claims 5 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cavanaugh, Jr. and O'Connor et al, as applied to claims 1, 3-4, 6-7, 11-14 and 16-17 above, and further in view of U.S. Patent No. 5,028,413 to Bianchi et al.

Cavanaugh, Jr. and O'Connor et al. are applied as discussed above. The references teach a topical composition for oral treatment comprising an aqueous solution of tromethamine salt of diclofenac with the recited concentration and pH limitations. Cavanaugh, Jr. furthermore teaches that it may desirable to provide a fluoride ion source in the composition as an anticaries agent (see column 7, lines 45-59, in particular.)

Cavanaugh, Jr. and O'Connor et al. do not specifically teach providing a gelling agent comprising a block copolymer of polyethylene glycol and polypropylene glycol.

Bianchi et al. teaches an aqueous-based dentrifice composition containing a polyoxyethylene polyoxypropylene block copolymer gelling agent (see abstract, in particular.) Bianchi et al. teaches that the composition having the block copolymer provides enhanced lubricating properties, and allows a high degree of fluoride delivery to the teeth (see column 2, lines 4-11.)

Accordingly, one of ordinary skill in the art would have found it obvious at the time the invention was made to provide the gelling agent of Bianchi et al. in the

composition of Cavanaugh, Jr. and O'Connor et al, with the expectation of achieving a composition suitable for topical treatment of oral disorders, and having improved lubricating properties and allowing for the incorporation of the anticaries agent fluoride ion.

Response to Arguments

Applicant's arguments filed December 15, 2005 with regards to the rejection of the claims over Cavanaugh, O'Connor and Bianchi have been fully considered but they are not persuasive.

In particular, Applicant's argue that Cavanaugh, Jr. et al. does not teach diclofenac as a NSAID. The Examiner respectfully refers Applicants to the abstract, column 1, lines 40-55, and column 3, lines 10-20, where Cavanaugh teaches that NSAIDs are provided in a composition for the oral cavity, and teaches that diclofenac is known as a non-steroidal anti-inflammatory drug suitable for topical application.

Applicants further argue that the composition is not obvious over Cavanaugh because Cavanaugh specifies a preferred pH that is lower than that claimed and a preferred concentration of NSAID that is higher than that claimed. The Examiner respectfully notes that Cavanaugh teaches general ranges of pH and concentration that overlap and/or encompass those claimed, as discussed above. It is noted that "[W]here

the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Applicants furthermore argue that it is not obvious to combine the diclofenac salt of O'Connor et al. in to the composition of Cavanaugh, Jr et al, because O'Connor et al. does not teach the specific pH and concentration ranges as recited. The Examiner notes that O'Connor does not specifically exemplify a diclofenac composition having all of the pH and concentration limitations as recited in the amended and newly presented claims. However, Cavanaugh teaches general pH and NSAID concentration ranges that are suitable for the oral composition, and that overlap and/or encompass the ranges as claimed. Accordingly, it would have been obvious to provide the diclofenac NSAID salt of O'Connor et al. into the composition of Cavanaugh and in the ranges set forth by Cavanaugh, with the expectation of providing a suitable oral formulation. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abigail M. Cotton whose telephone number is (571) 272-8779. The examiner can normally be reached on 9:30-6:00, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AMC